

ASSEMBLY BILL

No. 1317

Introduced by Assembly Member Ruskin

February 22, 2005

An act to add and repeal Sections 100854 and 100855 of, and to repeal and add Article 3 (commencing with Section 100825) of Chapter 4 of Part 1 of Division 101 of, the Health and Safety Code, relating to environmental laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 1317, as introduced, Ruskin. Environmental laboratories.

Existing law requires a laboratory that performs analysis for regulatory purposes of drinking water, wastewater, air, hazardous waste, and contaminated soils or sediments to obtain certification by the State Department of Health Services or, in the alternative, if appropriate, to obtain accreditation under the National Environmental Laboratory Accreditation Program (NELAP).

This bill would repeal, recast, and reenact those provisions.

Among other things, the bill would authorize the department to offer both state accreditation and NELAP accreditation. The bill would set forth the duties and responsibilities of the department in accrediting and monitoring environmental laboratories. It would require the department to appoint a multidisciplinary committee to provide assistance, advice, and recommendations to the department regarding technical and scientific aspects of laboratory accreditation. The bill would authorize an administrative hearing when the department denies, suspends, or revokes a laboratory's accreditation.

The bill would require any fees and civil penalties collected pursuant to the bill to be deposited in the Environmental Laboratory

Improvement Fund, to be available upon appropriation by the Legislature for purposes of the accreditation program.

Because, in addition to civil penalties, the bill would also impose criminal penalties for violation of certain of its requirements, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Article 3 (commencing with Section 100825) of
2 Chapter 4 of Part 1 of Division 101 of the Health and Safety
3 Code is repealed.

4 SEC. 2. Article 3 (commencing with Section 100825) is
5 added to Chapter 4 of Part 1 of Division 101 of the Health and
6 Safety Code, to read:

7
8 Article 3. Environmental Laboratories
9

10 100825. (a) This article shall be known, and may be cited, as
11 the Environmental Laboratory Accreditation Act.

12 (b) Laboratories that perform analyses on any combination of
13 environmental samples, or raw or processed agricultural products
14 for regulatory purposes shall obtain a certificate of accreditation
15 pursuant to this article.

16 (c) Unless the express language or context requires otherwise,
17 the definitions in this article shall govern the construction of the
18 article.

19 (1) "Accreditation" means the recognition of a laboratory by
20 the department to conduct analyses of environmental samples for
21 regulatory purposes.

22 (2) "Assessor body" means the organization that actually
23 executes the accreditation process, including receiving and

1 reviewing applications, documents, PT sample results, and onsite
2 assessments.

3 (3) "Certificate" means a document issued by the department
4 to a laboratory that has received accreditation pursuant to this
5 article.

6 (4) "Department" means the State Department of Health
7 Services.

8 (5) "Environmental samples" means potable and nonpotable
9 surface waters or groundwaters, soils and sediments, hazardous
10 wastes, biological materials, or any other environmental sample
11 designated for regulatory purposes.

12 (6) "NELAC" means the National Environmental Laboratory
13 Accreditation Conference.

14 (7) "NELAC standards" refer to the requirements found in
15 EPA publication number 600/R-98/151, November 1998, and
16 any subsequent amendments that are adopted by EPA or the
17 national program.

18 (8) "NELAP" means the National Environmental Laboratory
19 Accreditation Program established by NELAC.

20 (9) "NELAP accreditation" means the accreditation of a
21 laboratory that has met the requirements of the NELAC
22 standards, and the requirements of this article.

23 (10) "NELAP accredited laboratory" means a laboratory that
24 has met the standards of NELAC and has been accredited by a
25 primary or secondary NELAP recognized accrediting authority.

26 (11) "NELAP recognized accrediting authority" means a
27 state agency that is authorized by NELAP to accredit
28 laboratories.

29 (12) "NELAP recognized primary accrediting authority"
30 means a state agency that is responsible for the accreditation of
31 environmental laboratories within that state or that performs the
32 primary accreditation of a lab from a non-NELAP state or where
33 the laboratory's home state does not offer accreditation in a given
34 field of accreditation.

35 (13) "NELAP recognized secondary accrediting authority"
36 means a state agency that is authorized by NELAP to accredit
37 environmental laboratories within that state that have been
38 accredited by a NELAP-approved accrediting authority in
39 another state.

1 (14) “Proficiency testing (PT)” is a means of evaluating a
2 laboratory’s performance under controlled conditions relative to
3 a given set of criteria through analysis of unknown samples
4 provided by an external source.

5 (15) “PT sample” means a sample used for proficiency testing.

6 (16) “Regulatory purposes” means a statutory or regulatory
7 requirement of a state board, office, or department, or of a
8 division or program that requires a laboratory certified under this
9 section, or of the Department of Fish and Game, or of any
10 another state or federal agency that requires a laboratory to be
11 accredited.

12 (17) “Revocation” means the permanent loss of a certificate of
13 accreditation, including all units and fields of accreditation for
14 state accreditation and all fields of accreditation for NELAP
15 accreditation.

16 (18) “State accreditation” means accreditation of a laboratory,
17 which has met the requirements of this article and regulations
18 adopted by the department pursuant to this article.

19 (19) “Suspension” means the temporary loss of a unit or field
20 of accreditation.

21 100827. A laboratory accredited by the department shall
22 report, in accordance with the request for analysis, the full and
23 complete results of all detected contaminants and pollutants to
24 the person or entity that submitted the material for testing in a
25 timely fashion. The department may adopt regulations to
26 establish reporting requirements for this section.

27 100829. The department may do all of the following related to
28 accrediting environmental laboratories in the state:

29 (a) Offer both state accreditation and NELAP accreditation,
30 which shall be considered equivalent for regulatory activities
31 covered by this article.

32 (b) Adopt regulations to establish the accreditation procedures
33 for both types of accreditation.

34 (c) Retain exclusive authority to grant NELAP accreditation.

35 (d) Accept certificates of accreditation from laboratories that
36 have been accredited by other NELAP recognized accrediting
37 authorities.

38 (e) Adopt regulations to establish procedures for recognizing
39 the accreditation of laboratories located outside California for
40 activities regulated under this article.

1 (f) (1) Notwithstanding Sections 100854 and 100855, adopt
2 regulations for the collection of laboratory accreditation fees.

3 (2) Fees collected under this section shall be adjusted annually
4 as provided in Section 100425. The adjustment shall be rounded
5 to the nearest whole dollar.

6 (3) Fees paid by individual laboratories shall be proportional
7 to costs incurred by the department in the process of
8 accreditation.

9 (4) Fees shall be set for the two types of accreditation
10 provided for in subdivision (a).

11 (5) Programs operated under this article shall be fully
12 fee-supported.

13 100830. The department may do all of the following:

14 (a) Adopt regulations establishing requirements for both types
15 of accreditation. The regulations shall include, but not be limited
16 to, all of the following:

17 (1) Laboratory personnel.

18 (2) Quality assurance procedures.

19 (3) Laboratory equipment.

20 (4) Facilities.

21 (5) Standard operating procedures.

22 (6) Proficiency testing.

23 (7) Onsite assessments.

24 (8) Recordkeeping.

25 (9) Units and fields of accreditation.

26 (b) Adopt regulations establishing conditions under which the
27 department may issue, deny, or suspend a certificate of
28 accreditation for individual units or fields. Suspension and denial
29 of units or fields of accreditation shall be based on a laboratory's
30 failure to comply with this article and regulations adopted
31 thereunder.

32 100832. (a) The department shall appoint a multidisciplinary
33 committee to assist, advise, and make recommendations
34 regarding technical and scientific matters concerning the
35 accreditation of environmental laboratories.

36 (b) Appointments to the committee shall be made from lists of
37 nominees solicited by the department, and shall provide adequate
38 representation of interested parties and environmental
39 laboratories subject to this article.

1 (c) Subcommittees of the committee may be appointed by the
2 department, consisting of committee members and other persons
3 having particular knowledge of a subject area, for the purpose of
4 assisting the department with special problems and making
5 recommendations to the committee for consideration in the
6 establishment of regulations.

7 (d) The department shall determine the terms of office of
8 appointees to the committee and any subcommittee.

9 (e) Members of the committee and of any subcommittee shall
10 serve without compensation and shall pay their own expenses
11 incurred as a result of attending meetings or engaging in any
12 other activity pursuant to this section.

13 100834. (a) In order to carry out the purpose of this article,
14 the department may do all of the following:

15 (1) Enter and inspect, on an announce or unannounced basis, a
16 building, premises, equipment, materials, records, or information
17 at a reasonable time to secure compliance with, or prevent
18 violation of, this article or the regulations adopted pursuant
19 thereto.

20 (2) Inspect, photograph, or copy a record, report, test result, or
21 information related to the requirements of this article or the
22 regulations adopted thereunder.

23 (b) If a laboratory that is accredited or seeks to be accredited
24 by the department under this article refuses entry of a department
25 auditor or assessor, agent, investigator, or duly authorized
26 representative at a reasonable time for either the announced or
27 unannounced onsite assessment to determine compliance with
28 this article or the regulations adopted thereunder, the refusal of
29 entry shall constitute grounds for denial of the accreditation
30 application or revocation of the existing certificate.

31 100836. It shall be a misdemeanor, punishable by a fine of not
32 more than one thousand dollars (\$1,000) for each incident, for
33 any person to prevent, interfere with, or attempt to impede in any
34 way, any duly authorized representative of the department from
35 undertaking the activities authorized by this article.

36 100838. (a) Any person who knowingly withholds
37 information regarding an imminent and substantial danger to the
38 public health or safety when the information has been requested
39 in writing by the department and is required by the department in
40 order to carry out its responsibilities pursuant to this article, may,

1 upon conviction, be punished by a fine of not more than
2 twenty-five thousand dollars (\$25,000) for each day of violation,
3 or by imprisonment in the county jail not to exceed one year, or
4 by both the fine and imprisonment.

5 (b) Following an initial conviction under this section, if a
6 person is convicted of a second or subsequent violation of this
7 section, he or she may be punished by imprisonment in the state
8 prison for up to 24 months, or in the county jail for not to exceed
9 one year, or by a fine of not less than two thousand dollars
10 (\$2,000) or more than fifty thousand dollars (\$50,000) per each
11 day of violation, or by both the fine and imprisonment.

12 (c) The sanctions set forth in this section shall also apply to
13 NELAP-accredited laboratories.

14 100840. (a) Any person who: (1) knowingly makes any false
15 statement or representation in any application, record, other
16 document submitted, maintained, or used for purposes of
17 compliance with this article, or (2) prevents, interferes with, or
18 attempts to impede in any way, any duly authorized
19 representative of the department from undertaking the activities
20 authorized by this article, or (3) destroys, alters, or conceals any
21 record required to be maintained pursuant to this article, or (4)
22 has in his or her possession any record required to be maintained
23 pursuant to this article may that has been altered or concealed,
24 may be liable for a civil penalty not to exceed five thousand
25 dollars (\$5,000) payable to the department for each separate
26 violation, or for continuing violations, for each day that violation
27 continues.

28 (b) Any person who operates a laboratory for purposes
29 specified in this article who is not accredited by the department
30 pursuant to this article may be liable, as determined by the court,
31 for a civil penalty not to exceed five thousand dollars (\$5,000)
32 payable to the department for each separate violation, or for
33 continuing violations, for each day that violation continues.

34 (c) Any laboratory that advertises or holds itself out to the
35 public or its clients as having been certified for any unit of
36 accreditation without having a valid and current certificate in
37 each unit and field of accreditation identified by the
38 advertisement or other representation may be liable, as
39 determined by the court, for a civil penalty not to exceed one

1 thousand dollars (\$1,000) payable to the department, or for
2 continuing violations, for each day that violation continues.

3 (d) Each civil penalty imposed for any separate violation
4 pursuant to this section shall be separate and in addition to any
5 other civil penalty imposed pursuant to this section or any other
6 provision of law.

7 100842. Whenever the department determines that a person
8 has violated or is violating this article, or any certificate,
9 regulation, or requirement issued or adopted pursuant to this
10 article, the director may issue an order directing immediate
11 compliance or directing compliance in accordance with a time
12 schedule set by the department. Failure to comply with this
13 direction shall result in revocation of the certificate of
14 accreditation, or civil penalties not to exceed one thousand
15 dollars (\$1,000) payable to the department for each day of
16 noncompliance.

17 100844. The remedies provided by this article are cumulative
18 and shall not be construed as restricting any remedy, provisional
19 or otherwise, provided by law for the benefit of any party. No
20 judgment obtained pursuant to this article shall preclude any
21 party from obtaining additional relief based upon the same facts.

22 100846. (a) Revocation shall apply to an entire certificate of
23 accreditation including all units and fields of accreditation issued
24 to a laboratory for state accreditation and fields of accreditation
25 for NELAP accreditation.

26 (b) The department may revoke any certificate of accreditation
27 issued under this chapter for any of the following reasons:

28 (1) Violation by the laboratory owner of, or aiding, abetting,
29 or permitting the violation of, Section 100827, 100834, 100836,
30 100838, 100840, or 100842.

31 (2) Proof that the certificate holder or owner has made false
32 statements in any material regard on the application for
33 accreditation.

34 (3) (A) Conviction of a laboratory owner of any crime that is
35 substantially related to the qualifications or duties of that owner,
36 and that is related to the functions of the laboratory.

37 (B) For purposes of this paragraph, "conviction" means a plea
38 or verdict of guilty or a conviction following a plea of nolo
39 contendere.

1 100848. (a) Upon written notification that the department has
2 determined that an application for accreditation for a unit or field
3 of accreditation shall be denied, or existing units or fields of
4 accreditation shall be suspended from an existing certificate, or
5 that an entire certificate of accreditation shall be revoked, the
6 applicant or certificate holder may request an administrative
7 hearing by submitting a written request to the department within
8 20 business days of receipt of the written notification.

9 (b) Upon receipt of a written request, the department shall
10 hold an administrative hearing pursuant to the procedures
11 specified in Section 100171, except where those procedures are
12 inconsistent with this article.

13 (c) The department may adopt regulations necessary to enforce
14 this section.

15 100850. A NELAP-accredited laboratory, upon suspension,
16 revocation, or withdrawal of its NELAP accreditation, shall do
17 both of the following:

18 (a) Discontinue use of all catalogs, advertising, business
19 solicitations, proposals, quotations, or materials that contain
20 reference to the laboratory's past accreditation status.

21 (b) Return its certificate of NELAP accreditation to the
22 accrediting authority.

23 100852. Fees and civil penalties collected under this article
24 shall be deposited in the Environmental Laboratory Improvement
25 Fund, which is hereby continued within the State Treasury.
26 Moneys in the fund shall be available for expenditure by the
27 department for the purposes of this article, upon appropriation by
28 the Legislature.

29 100853. All regulations adopted by the department pursuant
30 to this article, as they read immediately preceding January 1,
31 2006, shall remain in full force and effect until repealed or
32 amended by the department in accordance with the rulemaking
33 provisions of the Administrative Procedure Act, Chapter 3.5
34 (commencing with Section 11340) of Part 1 of Division 3 of Title
35 2 of the Government Code.

36 SEC. 3. No reimbursement is required by this act pursuant to
37 Section 6 of Article XIII B of the California Constitution because
38 the only costs that may be incurred by a local agency or school
39 district will be incurred because this act creates a new crime or
40 infraction, eliminates a crime or infraction, or changes the

- 1 penalty for a crime or infraction, within the meaning of Section
- 2 17556 of the Government Code, or changes the definition of a
- 3 crime within the meaning of Section 6 of Article XIII B of the
- 4 California Constitution.

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